Reference 8

RECOMMENDATIONS FOR EVALUATING THE SAFETY OF IRRADIATED FOODS

FINAL REPORT

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Prepared for the Director, Bureau of Foods, FDA

MEMBERSHIP OF THE IRRADIATED FOOD COMMITTEE

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TESTING

Foods irradiated at doses above 100 Krad and comprising more than 0.01% of the diet are estimated to contain URPs in sufficient quantity to warrant toxicological evaluation. The non-mammalian mutagenicity tests offer a level of sensitivity not practically attainable in whole animal tests, and recalling that many URPs may be similar chemically to substances occurring naturally in foods, these tests are considered appropriate tools to evaluate the potential carcinogenicity of irradiated foods. The tests recommended are 1) gene mutations in bacteria, with and without metabolic activation, 2) gene mutations in cultured mammalian cells, 3) DNA repair in mammalian cells, and 4) recessive lethal mutations in Drosophila. These test are considered to be the minimum battery. Requests for substitutions for any of the above tests should be justified and will be considered on a case by case basis.

Because of the anticipated low level of individual radiolytic products present in the whole irradiated food, the above tests must be performed on extracts in which the concentration of radiolytic products is maximized. Also, many of the radiolytic products from polysaccharides and proteins will be large molecules and will not penetrate the cell membrane in the *in vitro* systems, hence the use of enzyme digests is recommended prior to the concentration of URPs.

In addition to the short-term mutagenicity tests, foods irradiated at doses above 100 krad must be evaluated in 90-day feeding studies in two species (one rodent, one non-rodent). The 90-day rodent test should include *in utero* exposure. To assure that the test animals are exposed to the highest concentration of radiolytic products possible, the irradiated food may be lyophilized and incorporated into the animal diet at the highest concentration that does not compromise the nutritional requirements of the test species (see Appendix IV). It is not necessary to test enzyme digests of the irradiated food in these tests since each test animal provides digestion of food components before systemic absorption occurs. Higher doses of particular radiolytic products may be obtained if the selectively extracted and concentrated material used in the short-term tests is employed; however, it is recognized that much greater quantities would be needed for *in vivo* testing and thus would make this latter suggestion extremely difficult and expensive to effect in any practical sense.